JUN 1 0 2002

K010952

510(K) SUMMARY

Submitted By

Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
May 3, 2002

Names of Device

Trade Name:	SURGISIS® Periodontal Membrane
Common/Usual Name:	Periodontal barrier membrane
Proposed classification name:	Bone filling augmentation material 21 CFR 872.3640 (76LYC)

Intended Use

SURGISIS Periodontal Membrane is a bioabsorbable, implantable material intended to aid in the treatment of periodontal defects. The device is provided sterile and intended for one-time use.

Predicate Devices

SURGISIS® Mesh (K980431) manufactured by Cook Biotech Incorporated
BioMend® (K924408) manufactured by Integra Life Sciences
Bio-Gide® (K960724) manufactured by ED. GEISTLICH PHARMA AG
GORE RESOLUT XT (K973594) manufactured by W. L. Gore & Associates, Inc.

Device Description

SURGISIS Periodontal Membrane is manufactured from porcine small intestinal submucosa and is supplied in sheet form in sizes ranging from 0.5 cm^2 to 50 cm^2. The device is packaged in sterile, sealed double pouches.

Substantial Equivalence

SURGISIS Periodontal Membrane is substantially equivalent to the predicate devices, having similar intended use and technological characteristics. The substantially equivalent determination under the Federal Food, Drug, and Cosmetic Act is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.

Discussion of Tests and Test Results

SURGISIS Periodontal Membrane was subjected to a panel of tests to assess integrity, suture hole elongation, biocompatibility, resorption/remodeling, and *in vivo* performance as a barrier membrane. SURGISIS Periodontal Membrane passed the requirements of all tests, providing reasonable assurance of device performance for its intended use and substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

Mr. Mark Bleyer
President
Cook Biotech, Incorporated
3055 Kent Avenue
West Lafayette, Indiana 47906-1076

Re: K010952
Trade/Device Name: SURGISIS® Periodontal Membrane
Regulation Number: 872.3640
Regulation Name: Periodontal Barrier Membrane
Regulatory Class: Unclassified
Product Code: LYC
Dated: May 3, 2002
Received: May 6, 2002

Dear Mr.Bleyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010952

510(k) Number (if known): **K010952**

Device Name: **SURGISIS® Periodontal Membrane**

Indications For Use: SURGISIS Periodontal Membrane is a bioabsorbable, implantable material intended to aid in the treatment of periodontal defects. The device is provided sterile and intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
K010952

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____